

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

VELTEK ASSOCIATES, INC.
15 Lee Boulevard
Great Valley Corporate Center
Malvern, PA 19355
and
ARTHUR VELLUTATO
15 Lee Boulevard
Great Valley Corporate Center
Malvern, PA 19355

Plaintiffs,

v.

STERIS CORPORATION
5960 Heisley Road
Mentor, OH 44060

Defendant.

DEFENDANT'S ANSWER TO COMPLAINT AND COUNTERCLAIM

Defendant, STERIS Corporation (“STERIS” or “Defendant”) states for its Answer to the Complaint and its Counterclaim as follows:

JURISDICTION AND VENUE

1. STERIS admits that paragraph 1 of the Complaint purports to allege a civil action for patent infringement and that this Court has original subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

2. STERIS admits that this Court has personal jurisdiction over STERIS as to the specific allegations of patent infringement alleged in the Complaint. STERIS denies that it has

infringed United States Patent No. 6,607,695 in the Commonwealth of Pennsylvania by either making, using, selling or offering to sell infringing products in Pennsylvania including its aerosol Septihol WFI Sterile Aerosol Alcohol Solution.

3. STERIS admits that venue is proper in this district and that it is subject to personal jurisdiction in this district.

PARTIES

4. Answering paragraph 4, STERIS lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of paragraph 4 of the Complaint and on that basis denies them.

5. Answering paragraph 5, STERIS lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations, and on that basis denies them.

6. STERIS admits the allegations of paragraph 6 of the Complaint.

7. STERIS denies the allegations of paragraph 7 of the Complaint.

COUNT I

Alleged Infringement of U.S. Patent No. 6,607,695

8. STERIS admits that Exhibit A is a copy of the '695 Patent and that it issued on August 19, 2003. STERIS further admits that the title of the '695 Patent is "Method of Sterilization." Except as expressly admitted herein, STERIS denies the allegations of paragraph 8 of the Complaint.

9. STERIS lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of paragraph 9 of the Complaint and on that basis denies them.

10. STERIS lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of paragraph 10 of the Complaint and on that basis denies them.

11. STERIS denies the allegations of paragraph 11 of the Complaint.

12. STERIS denies the allegations of paragraph 12 of the Complaint.

13. STERIS denies the allegations of paragraph 13 of the Complaint.

14. STERIS denies the allegations of paragraph 14 of the Complaint.

JURY DEMAND

15. Paragraph 15 of the Complaint is a jury demand and is not an averment to which a response is required under the *Federal Rules of Civil Procedure*.

AFFIRMATIVE DEFENSES

First Affirmative Defense

16. STERIS has not infringed, and is not infringing, any valid and enforceable claim of the '695 Patent, either directly, contributorily, by inducement, or otherwise.

Second Affirmative Defense

17. The '695 Patent, including each claim thereof, is invalid for failure to comply with one or more requirements of the patent laws, including without limitation the requirements of 35 U.S.C. §§ 102, 103, 112, and/or 132. Specifically, the claims of the '695 Patent are invalid based on at least the following:

a. The claims of the '695 Patent are invalid for lack of novelty under 35 U.S.C. § 102 and/or obviousness under 35 U.S.C. § 103 based on prior art patents and publications, prior knowledge and prior inventions of others;

b. The claims of the '695 Patent are invalid for lack of novelty under 35 U.S.C. § 102 and/or obviousness under 35 U.S.C. § 103, based on one or more offers to sell, sales, and/or public uses;

c. The claims of the '695 Patent are invalid for failure to satisfy the written description and/or enablement requirements of 35 U.S.C. § 112, ¶ 1;

d. The claims of the '695 Patent are invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2;

e. The claims of the '695 Patent are invalid since new matter was impermissibly added to the application for the '695 Patent in violation of 35 U.S.C. § 132.

Third Affirmative Defense

18. Plaintiffs are estopped from asserting the claims of the '695 Patent against STERIS or otherwise asserting that the claims should be construed to cover STERIS's products or processes, either literally or under the doctrine of equivalents.

Fourth Affirmative Defense

19. Plaintiffs' claims are barred by the doctrines of laches, estoppel, waiver, unclean hands, and other equitable remedies.

Fifth Affirmative Defense

20. The '695 Patent is unenforceable because of inequitable conduct committed during the prosecution of the '695 patent application, during the prosecution of its parent application which resulted in Patent 6,333,006 ("the '006 Patent"), and during the prosecution of its grandparent application which resulted in patent 6,123,900 ("the '900 Patent"). On information and belief, Arthur Vellutato, attorneys who prepared and/or prosecuted the '900,

'006, and/or '695 patent applications, and/or others associated with the filing or prosecution of the applications, intentionally, and with deceptive intent, failed to disclose known, material prior art and information to the United States Patent and Trademark Office("PTO") including, failing to call the PTO examiner's attention to (a) two publications by Veltek Associates that appeared in the March 1992 issue of the magazine "Clean Rooms," (b) offers to sell, sales, and/or public uses of patented products, and products made by the patented process, by Veltek Associates and CCL Industries Limited ("CCL"), (c) summary judgment motions filed by Miller Products Co. in Miller's suit against Veltek Associates, and (d) the Decision of the Board of Patent Appeals and Interferences rendered during the pendency of the application for the '900 Patent, the latter of which was not brought to the attention of the examiner handling the applications for the '006 and '695 Patents.

Sixth Affirmative Defense

21. Plaintiffs brought this action in bad faith, making it an exceptional case and thereby entitling STERIS to its costs and attorneys fees pursuant to 35 U.S.C. § 285.

Reservation of Rights to Assert Other Affirmative Defenses

22. STERIS reserves the right to assert additional affirmative defenses as discovery proceeds.

COUNTERCLAIM

Nature of the Action

1. STERIS brings this counterclaim for a declaratory judgment that United States Patent No. 6,607,695 (the '695 Patent) is invalid, unenforceable, and not infringed.

The Parties

2. Defendant and Counterclaimant STERIS is an Ohio Corporation having its principal palace of business in Mentor, Ohio.

3. On information and belief, Plaintiff and Counterclaim Defendant Veltek Associates is a Pennsylvania corporation having its principal place of business at 15 Lee Boulevard, Great Valley Corporate Center, Malvern, Pennsylvania 19355.

4. On information and belief, Plaintiff and Counterclaim Defendant Arthur Vellutato is an individual residing in the Commonwealth of Pennsylvania.

Jurisdiction

5. This action for a declaration of no infringement, invalidity, and unenforceability of the '695 patent arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the United States patent laws, 35 U.S.C. §§ 1, *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Veltek and Vellutato have alleged that Counterclaim Plaintiff STERIS is infringing and/or has infringed the '695 Patent, and STERIS has denied this allegation and it asserts that the '695 Patent is invalid and unenforceable. Therefore, the validity, enforceability and infringement of the '695 patent are justiciable issues between the parties to the Counterclaim that are susceptible of adjudication under the Declaratory Judgment Act.

COUNT 1

Declaratory Judgment of Patent Invalidity

7. The '695 Patent, including each claim thereof, is invalid for failure to comply with one or more requirements of the patent laws, including without limitation the requirements of 35 U.S.C. §§ 102, 103, 112, and/or 132. Specifically, the claims of the '695 Patent are invalid based on at least the following:

- a. The claims of the '695 Patent are invalid for lack of novelty under 35 U.S.C. § 102 and/or obviousness under 35 U.S.C. § 103 based on prior art patents and publications, prior knowledge and prior inventions of others;
- b. The claims of the '695 Patent are invalid for lack of novelty under 35 U.S.C. § 102 and/or obviousness under 35 U.S.C. § 103, based on one or more offers to sell, sales, and/or public uses;
- c. The claims of the '695 Patent are invalid for failure to satisfy the written description and/or enablement requirements of 35 U.S.C. § 112, ¶ 1;
- d. The claims of the '695 Patent are invalid for indefiniteness under 35 U.S.C. § 112, ¶ 2;
- e. The claims of the '695 Patent are invalid since new matter was impermissibly added to the application for the '695 Patent in violation of 35 U.S.C. § 132.

COUNT II

Declaration of Noninfringement of the '695 Patent

8. Defendants incorporate and re-allege paragraphs 1-7 of this Counterclaim.
9. STERIS has not infringed, and is not infringing, any valid and enforceable claim of the '695 Patent, either directly, contributory, by inducement or otherwise.
10. Plaintiffs are estopped from asserting the claims of the '695 Patent against STERIS or otherwise asserting that the claims of the '695 Patent should be construed to cover STERIS' products or processes, either literally or under the doctrine of equivalents.
11. Plaintiffs are barred from asserting that Defendant STERIS has infringed or is infringing the '695 Patent by the doctrines of laches, estoppel, waiver, unclean hands, and other equitable remedies.

COUNT III

Declaration of Unenforceability for Inequitable Conduct

12. Defendants incorporate and re-allege paragraphs 1-11 of the Counterclaim.
13. The '695 Patent is unenforceable because of inequitable conduct committed during the prosecution of the '695 patent application, during the prosecution of its parent application which resulted in Patent 6,333,006 ("the '006 Patent"), and during the prosecution of its grandparent application which resulted in Patent 6,123,900 ("the '900 Patent"). On information and belief, Arthur Vellutato, attorneys who prepared and/or prosecuted the '900, '006, and/or '695 patent applications, and/or others associated with the filing or prosecution of the applications, intentionally, and with deceptive intent, failed to disclose known, material prior art and information to the United States Patent and Trademark Office("PTO") including, failing to

call the PTO examiner's attention to (a) two publications by Veltek Associates that appeared in the March 1992 issue of the magazine "Clean Rooms," (b) offers to sell, sales, and/or public uses of patented products, and products made by the patented process, by Veltek Associates and CCL Industries Limited ("CCL"), (c) summary judgment motions filed by Miller Products Co. in Miller's suit against Veltek Associates, and (d) the Decision of the Board of Patent Appeals and Interferences rendered during the pendency of the application for the '900 Patent, the latter of which was not brought to the attention of the examiner handling the applications for the '006 and '695 Patents

DEMANDS FOR RELIEF

WHEREFORE, STERIS demands judgment in its favor and against Plaintiffs as follows:

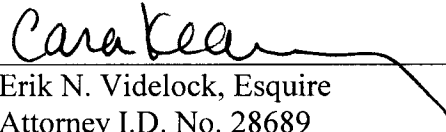
- A. That Plaintiffs take nothing by way of their Complaint;
- B. That the Court declare that the claims of the '695 Patent are invalid;
- C. That the Court declare that the claims of the '695 Patent are unenforceable;
- D. That the Court declare that STERIS has not infringed the '695 Patent;
- E. That the Court declare this an exceptional case pursuant to 35 U.S.C. § 285 and that STERIS be awarded its attorneys fees and costs incurred in connection with this action; and
- F. That STERIS have such other and further relief as the Court deems proper.

DEMAND FOR A JURY TRIAL

Pursuant to *Fed. R. Civ. P.* 38(b), STERIS demands a trial by jury of any and all issues so triable.

Respectfully submitted,

PEPPER HAMILTON LLP



Erik N. Videlock, Esquire
Attorney I.D. No. 28689
Cara M. Kearney, Esquire
Attorney I.D. No. 93198
3000 Two Logan Square
18th and Arch Streets
Philadelphia, PA 19103-2799
(215) 981-4000

Attorneys for Defendant

CO-COUNSEL:

R. Terrance Rader (P28747)
Charles W. Bradley (00272523)
Steven R. Hansen (P69144)
RADER, FISHMAN & GRAUER PLLC
39533 Woodward Avenue, Suite 140
Bloomfield Hills, Michigan 48304
Telephone: 248-594-0600
Facsimile: 248-594-0610
rtr@raderfishman.com

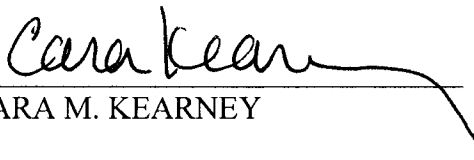
Dated: October 15, 2007

CERTIFICATE OF SERVICE

I hereby certify that on October 15, 2007 a copy of the foregoing DEFENDANT'S ANSWER TO COMPLAINT AND COUNTERCLAIM was electronically filed via ECF with the Clerk of Court, which will send notification of such filing to counsel of record.

I hereby certify a copy of the foregoing was served by transmitting same via Overnight Mail on the following:

Grant S. Palmer, Esquire
Blank Rome Comisky & McCauley
One Logan Square
Philadelphia, PA 19103
Email: palmer@blankrome.com



CARA M. KEARNEY